IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of Hood, *et al.*	)	Date: August 24, 2009
	)	
Application No.: 09/930,788	)	Group Art Unit: 3627
	)	
Filed: August 15, 2001	)	Examiner: Frenel, Vanel
	)	
For: Customizable Handheld Computer Data Collection and Report Generation Software	)	Attorney Ref. No.: 121.02

APPELLANT'S BRIEF PURSUANT TO 37 C.F.R §41.37

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Sir:

Appellant submits this brief in accordance with the provisions of 37 C.F.R. § 41.37 in response to the Final Rejection mailed February 4, 2009. Appellant's Notice of Appeal was filed April 24, 2009. This Appeal Brief is therefore timely filed.

The filing of $270.00 associated with the filing of this document is being paid via EFS.

I. REAL PARTY IN INTEREST

The real party in interest herein is Andrew David Hood (Pine Grove, CA) and Jeffrey Scott Sliwa (Lake Worth, FL).

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

In the current application under appeal, claims 2, 4-6, 8, 13-16, 19-21, 23-25 and 35-36 are pending. Claims 1, 3, 7, 9-12, 17-18, 22, 36-34 and 37-40 have been cancelled and no claims have been withdrawn. The rejection of claims 2, 4-6, 8, 13-16, 19-21, 23-25 and 35-36 is appealed herein.

IV. STATUS OF AMENDMENTS

Appellant has submitted no amendments after the final rejection. All amendments prior to the close of prosecution on the merits have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

37 CFR § 41.31(c)(v) requires an appeal brief to contain a "concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters."

Independent claim 2 recites a system for gathering and managing patient medical data in which a handheld computing device has a computer-readable medium having stored thereon a plurality of instruction sequences, which, when executed by a processor, cause the process to perform the steps of (1) executing a first module for gathering patient medical information, wherein the first module displays a plurality of customized template based data entry screens, a means for receiving medical data through remote transmission, and a means for creating a natural language report and a data point-based searchable database from said medical information and wherein the natural language report has syntax and structure; (2) creating said customized template based data entry screens from the customized template based data entry screen data received from a

template manager having a means for substantially customizing the customized template based data entry screen data for use by the first module; (3) wherein at least one of the customized template based data entry screens correlates a set of modifiers to a body part; and (4) wherein the customized template based data entry screen data directs the function of the first module.

Independent claim 16 recites a software application for gathering and managing patient medical data, comprising (1) a first module for gathering patient medical information on a handheld computing device, the first module having a plurality of customized template based data entry screens, a means for receiving medical data through remote transmission, a means for receiving customized information, and a means for creating a natural language report and a data point-based searchable database from the medical information, wherein said natural language report has a syntax and a structure; (2) a template manager for creating customized template based data entry screens for use by the first module; (3) wherein the function of the first module is directed by said customized template based data entry screens; and (4) wherein at least one of said customized template based data entry screens allows a user to correlate a set of modifiers with a body part.

Independent claim 35 recites a system for creating customized medical data input screens, the system comprising (1) a handheld computing device having loaded in memory a first module for gathering patient medical information, the first module having a customized medical data entry screen that allows a user to input patient medical information; (2) a means for creating a natural language report and a searchable database from the medical information; (3) a second module having a means for customizing the screen, the natural language report, and the searchable database; and wherein the customization means is template based.

Independent claim 36 recites a system for gathering and managing patient medical data, the system comprising (1) a handheld computing device, the handheld computing device having a means of gathering specified regulatory data and having loaded in memory a computer module for gathering patient medical information, the module having a customized medical data entry screen that allows a user to input patient medical information; (2) a matrix within the data entry screen that allows a user to correlate a body part with a set of modifiers; (3) a second module

having a means for customizing the customized medical data entry screen and said matrix; and (4) wherein said customization means is template based.

The handheld device is described at least on page 10 lines 18-24, Page 5 lines 16-20, Page 7 line 20 through page 8 line 2, page 3 line 21 through page 4 line 2, page 10 lines 1-7, page 4 lines 7-21, page 10 line 17 through page 12 line 21, page 9 lines 6-15, the abstract and original claims of Appellants' application as filed.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant respectfully requests the Board of Patent Appeals and Interferences to review the following grounds of rejection on appeal:

1. Whether claims 2, 4-6, 8, 13-16, 19-21, 23-25 and 35-36 are patentable under 35 U.S.C. § 103(a) over U.S. Pat. No. 6,168,563 ("Brown") in view of U.S. Pat. No. 6,047,259 ("Campbell") and further in view of U.S. Pat. Pub. 2003/0036683 ("Kehr").

VII. ARGUMENTS

Appellant respectfully submits that claims 2, 4-6, 8, 13-16, 19-21, 23-25 and 35-36 are in proper form and are patentable over the prior art of record.

Legal discussion

The Examiner bears the initial burden of establishing a *prima facie* case of nonpatentability under § 103. *In re Oetiker,* 977 F.2d 1443, 1445 (Fed. Cir. 1992).

A *prima facie* case of obviousness requires a determination of (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the pertinent art. *KSR International* v. *Telejlex, Inc.,* 550 U.S. 398, 127. S.Ct. 1727, 167 L.Ed. 705, 710, 82 USPQ2d 1385 (2007), *quoting Graham* v. *John Deere Co. of Kansas City,* 383 U.S. 1, 17-18 (1966). The obviousness or nonobviousness of the subject matter is determined against this background. *Id.*

To find an invention obvious, the prior art, common knowledge, or the nature of the problem,

viewed through the eyes of an ordinary artisan, must have suggested all the elements of the claimed invention. *Dystar Textilfarben GMBH & Co* v. *CH Patrick Co.,* 464 F.3d 1356, 1361 (Fed. Cir. 2006). Likewise, when the prior art teaches away from a combination of elements and features, discovery of a successful means of combining them is more likely to be nonobvious. *KSR,* 167 L.Ed. at 1740. "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* at 1741, *quoting In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006).

As part of an obviousness determination, the Examiner can assess evidence related to secondary indicia of nonobviousness like commercial success, long-felt but unresolved needs, and the failure of others. *In re Kahn*, 78 USPQ2d 1329 at 1335 (Fed. Cir. 2006). See also *In re Kumar*, 76 USPQ2d 1048 at 1050 (Fed. Cir. 2005) ("An applicant may rebut a *prima facie* case of obviousness by providing a 'showing of facts supporting the opposite conclusion.' Such a showing dissipates the *prima facie* holding and requires the examiner to consider all of the evidence anew.") (*emphasis in original*).

The Applicants thus set forth objective evidence to show that the claimed subject matter would have been nonobvious. The Applicants respectfully request the Examiner consider the following rebuttal evidence including such secondary considerations as commercial success, long-felt but unsolved needs and failure of others.

Regarding a long-felt but unresolved need for the claimed subject matter, The Applicants recognize such facts are not the kind that cannot be questioned, and indeed that the Federal Circuit has held that precedent requires the Applicant to submit actual evidence of long-felt need rather than simply arguing such need existed. *In re Kahn*, 441 F.3d 977, 78 USPQ2d 1329 (Fed. Cir. 2006). Thus, in addition to the attached Declarations is evidence to show the Federal government has mandated that all Pre-hospital providers to collect data electronically. Exhibit 1 (Goals and Objectives of the National EMS Information System), and Exhibit 2 (the NHTSA's Agenda for the Future Implementation Guide, *see specifically* page 4 under the heading 'Information Systems') are indicative of this move toward electronic data recordation for EMS

providers. Indeed, the "Agenda for the Future" was first provided as far back as 1998, as evidenced by the history of NEMSIS timeline shown in Exhibit 3.

This and other factors described below have prompted a trend in the EMS industry toward the electronic collection of data while the EMS technician is still in the field. Davis Declaration ¶4. In many departments, such practices are recommended while in many others they are in fact required. Id.

Logically, there are financial reasons to implement such a system as well. For instance, conventionally there is a great deal of paper and physical files associated with medical data collection. Davis Declaration ¶4. For billing purposes, storage purposes and record keeping purposes, these documents are often moved, copied and mailed at great expense. Id. In addition, statistics and checks on the number of procedures performed by each technician are recorded for quality assurance purposes, and such data is more easily tracked electronically. Id. Moving to electronic record keeping is known to reduce these downsides as well as allow for better and often complete documentation and fewer lost calls due to oversight and physical papers being misplaced. Id. Finally, electronic data collection vastly improves the ability to track the effectiveness of current paramedicine in general. Id. This movement has been ongoing since at least the time of filing the present application. Id. There is thus a long-felt need for an electronic data collection system that can be used in the field.

As expected, the need to move to electronic data collection prompted many companies to attempt to provide suitable products. Davis Declaration ¶4. Indeed, competitors to the Applicants have built software for handheld platforms, but all have failed. Hood Declaration ¶5. The claimed subject matter in the present application has proven to work and be commercially successful whereas competitors' attempts have met with failure. Id.

The failure of others has to do with one of the claimed elements of the present invention, namely, the customizable nature of the system and its adaptability to small screens. From department to department and region to region, there are large differences in data collection requirements and requirements for interfacing with and documenting medical data. Davis Declaration ¶7. In order to create a system complex enough to meet the various documentation needs and to display and collect essentially unlimited amounts of data on a small handheld screen, the Applicants

developed the customized template approach defined in the specification and claims as "Template Manager". Hood Declaration ¶6.

Prior to the unveiling of the system claimed in the present application, solutions were rigid designs with minimal ability to adapt to the various demands of different departments. Davis Declaration ¶8. For instance, many competitors created systems for large governmental departments due to their use of the common Advanced Life Support (ALS) transporting standard and because customization costs for these larger systems were more easily recuperated. Id. Systems with customization capabilities to meet the needs of small and rural departments were not available before the introduction of the claimed system. Hood Declaration ¶7. The small departments are having difficulty meeting the federal mandate because not only do they have less funding to do so, but also because their small size does not allow competing systems to recuperate customization startup costs. Id.

Due to the high levels of customization offered by the present system, it has met the requirements for a wide variety of departments including very small departments, non-transporting departments, DIALYSIS and 'gurney car' services, etc. Hood Declaration ¶8. The success of the present system was based on the ability to use templates to create a system allowing the collection of wide range of data on a small screen. Id. The needs of these departments have been unmet by competing systems. Id.

Nearly all competitors have also attempted some sort of handheld hardware platform for EMS, but all have failed. Hood Declaration ¶9. The attempt of these competitors to develop the system again shows that there does exist a need for such a system. Id. The present system is the only system commercially successful on pocket-pc sized handheld devices, and meets the needs of providing a handheld hardware platform for EMS. Id. It is the high level of customization that has allowed the present system to be deployed for departments using displays as small as PDA type mobile phones. Id. Through use of the claimed template driven system of creating widely customizable interfaces for such displays, even small departments with specialized needs have quickly created and rolled out a handheld platform for EMS. Id.

As stated above, competitors have attempted to deploy a handheld hardware platform for EMS but have failed. Hood Declaration ¶10. Most failures stem from the fact that systems designed to

work on PC screens do not translate well to handheld screens. Id. Even large corporations such as Zoll and Medtronic have entered the market and had failures. Id. For instance, Medtronic pulled its system from the market because the system could not "adapt" or be customized to the customers' needs. Id. Furthermore, Zoll, the industry leader with the largest market share also pulled from the market a product that was an attempt at a handheld version of their software used on larger displays. Id. Such failures show the inherent problem of having success in displaying and collecting data for EMS Data collection on a small handheld device. Id. Other industry leaders, such as Med Media, attempted to produce successful handheld data recording devices for EMS but have since pulled their products because of failure. Id. The present application's disclosure and claims covering an approach of using customizable templates has made the Applicants' system vastly superior to systems implemented before it. Davis Declaration ¶9.

Regarding the commercial success of the system covered by the pending claims, the system is now in use in six states, with three military contracts, and is the main system used in San Diego County, which is the 6th largest EMS system in the United States. Hood Declaration ¶11. Furthermore, the system has not been the subject of significant advertising. Id. Unexpectedly, the customizable nature of the system has even allowed it to find success on very small mobile platforms. Id. Hence, the system has even been deployed on mobile phones, which due to their small size and the fact that they are already carried by ambulance and fire personnel are the ideal platform to meet state and locally mandated EMS agency requirements for ambulances. Id.

Conclusion

In summary, the prior art cited by the Examiner as well as software from all other handheld devices "respond" to inputs from the end user using templates. The present invention is a system that provides a program for a content expert to create a new interface for *each end user* depending on the end user's needs. As the end user's needs change, the content expert can customize and improve the interface for that customer as needed. This capability is important to meet the needs of all the diverse requirements of medical levels of care, types of service, documentation needs, data collection needs, and geographical differences in medical documentation.

The facts detailed above, along with the attached supporting evidence, show the recognition of a problem, the failure of others to meet the long-felt need, and the commercial success of the current Applicants' system to meet this need. The objective evidence presented above supports the conclusion that the invention would not have been obvious to a skilled artisan and that the prior art did not enable one skilled in the art to produce the now-claimed invention.

In light of the remarks and amendments detailed above, which address each rejection and objection by the Examiner, the Applicants respectfully request reconsideration and allowance of all pending claims.

Respectfully Submitted,

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Dated: August 24, 2009

VIII. EVIDENCE APPENDIX

Brown US 6,168,563 cited by the Examiner in an Office Action dated February 4, 2009.
Campbell US 6,047,259 cited by the Examiner in an Office Action dated February 4, 2009.
Kehr US 2003/0036683 cited by the Examiner in an Office Action dated February 4, 2009.

Exhibit 1 – National EMS Information System "Goals and Objectives", available at http://www.nemsis.org/theProject/whatIsNEMSIS/goalsAndObjectives.html, last accessed August 24, 2009

Exhibit 2 – EMS Implementation Guide – Summary of Recommendations as published by the National Highway Traffic Safety Administration – available at http://www.nhtsa.dot.gov/people/injury/ems/agenda/apenc.html, last accessed August 24, 2009

Exhibit 3 – National EMS Information System – History of NEMSIS – available at http://www.nemsis.org/theProject/historyofNemsis.html, last accessed August 24, 2009

Declaration of Andrew Hood, Appellant

Declaration of Dan Davis, Professor UC San Diego Emergency medicine, Regional Medical Director for Mercy Air Medical Services, UC San Diego Base Hospital Director and Board Certified ACEP.

IX. RELATED PROCEEDINGS APPENDIX

None.

X. CLAIMS APPENDIX

1.) (cancelled)

2.) (previously presented) A system for gathering and managing patient medical data in which a handheld computing device has a computer-readable medium having stored thereon a plurality of instruction sequences, which, when executed by a processor, cause the process to perform the steps of:

executing a first module for gathering patient medical information, wherein said first module displays a plurality of customized template based data entry screens, a means for receiving medical data through remote transmission, and a means for creating a natural language report and a data point-based searchable database from said medical information, said natural language report having syntax and structure;

creating said customized template based data entry screens from customized-template based data entry screen data received from a template manager having a means for substantially customizing said customized template based data entry screens data for use by said first module;

wherein at least one of said customized template based data entry screens correlates a set of modifiers to a body part; and

wherein said customized template based data entry screen data directs the function of said first module.

3.) (cancelled)

4.) (previously presented) The system according to claim 2, wherein said template manager additionally comprises a plurality of templates for creating said customized template based data entry screens.

5.) (previously presented) The system according to claim 4, wherein said template manager additionally comprises means for editing all aspects of said customized template based data entry screens, said syntax and structure of said natural language report, and said data-points.

6.) (previously presented) The system according to claim 5, wherein said first module additionally comprises means to delete at least one of said customized template based data entry screens.

7.) (cancelled)

8.) (previously presented) The system according to claim 5, wherein said template manager has means for customizing navigation between said plurality of customized template based data entry screens.

9.) – 12.) (cancelled)

13.) (previously presented) The system according to claim 8, additionally comprising a portable printer for printing out said natural language report.

14.) (previously presented) The system according to claim 13, wherein said template manager has a means for flagging certain data items as relevant for specific purposes.

15.) (previously presented) The system according to claim 14, wherein said searchable database has a plurality of items, and wherein each such item has a unique identifier, and wherein said customized information further comprises said unique identifier.

16.) (previously presented) A software application for gathering and managing patient medical data, comprising:

a first module for gathering patient medical information on a handheld computing device, said first module having a plurality of customized template based data entry screens, a means for receiving medical data through remote transmission, a means for receiving customized information, and a means for creating a natural language report and a data point-based searchable database from said medical information, wherein said natural language report has a syntax and a structure;

a template manager for creating customized template based data entry screens for use by said first module;

wherein the function of said first module is directed by said customized template based data entry screens; and

wherein at least one of said customized template based data entry screens allows a user to correlate a set of modifiers with a body part.

17.) – 18.) (cancelled)

19.) (currently amended) The software application according to claim 16, wherein said template manager additionally comprises a plurality of templates for creating said customized template based data entry screens.

20.) (previously presented) The software application according to claim 19, wherein said template manager additionally comprises means for editing all aspects of said customized template based data entry screens, said

natural language report, and said data points in said data point-based searchable database.

21.) (previously presented) The software application according to claim 20, wherein said first module additionally comprises means to delete at least one of said customized template based data entry screens.

22.) (cancelled)

23.) (previously presented) The system according to claim 21, wherein said template manager has a means for customizing navigation between said customized template based data entry screens.

24.) (previously presented) The software application according to claim 23, wherein said template manager has a means for controlling the syntax and structure of said natural language report.

25.) (previously presented) The software application according to claim 24, wherein said searchable database has a plurality of items, and wherein each such item has a unique identifier, and wherein said customized information further comprises said unique identifier.

26.) – 34.) (cancelled)

35.) (previously presented) A system for creating customized medical data input screens, comprising:

a handheld computing device, said handheld computing device having loaded in memory a first module for gathering patient medical information, said first module having a customized medical data entry screen, said screen allowing a user to input patient medical information;
a means for creating a natural language report and a searchable database from said medical information;
a second module having a means for customizing said screen, said natural language report, and said searchable database; and
wherein said customization means is template based.

36.) (previously presented) A system for gathering and managing patient medical data, comprising:

a handheld computing device, said handheld computing device having a means of gathering specified regulatory data and having loaded in memory a computer module for gathering patient medical information, said module having a customized medical data entry screen, said screen allowing a user to input patient medical information;

a matrix within said data entry screen, said matrix allowing a user to correlate a body part with a set of modifiers;
a second module having a means for customizing said customized medical data entry screen and said matrix; and
wherein said customization means is template based.

37.) – 40.) (cancelled)